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10/687,636	10/20/2003	Patrick Rambaud	0501-1017-1	1794

466 7590 05/16/2007  
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EXAMINER
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WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/687,636

Applicant(s)

RAMBAUD, PATRICK

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 11-14, 22 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-10, 15-21, 23-25, 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 8-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' response, filed 02/12/2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

#### *CORRECTION*

The Examiner indicated in the previous Office action, mailed 09/12/2006, that claims 1, 2, 4, 5, 8-10, 15-24, and 30-31 were under examination, and that claims 25-26 were cancelled. It is noted that applicant's originally elected claims 1-24 in the response, filed 03/15/2006. Applicant then amended claim 25 to depend from claim 1 and canceled claim 26. The Examiner did in fact examine amended claim 25 along with elected claims 1-24, however this was not made clear in the Office action mailed 09/12/2006. The Examiner would like to clarify for the record that claims 1, 2, 4, 5, 8-10, 15-25, and 30-31 should have been listed as being under examination in the Office action mailed 09/12/2006. An updated listing of the claims currently under examination is set forth below. The Examiner apologizes for any inconvenience this may have caused the applicant.

#### *ABSTRACT*

The revised abstract of the disclosure is acceptable.

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### *OBJECTIONS*

Claim 1 is objected to because of the following informalities: Claim 1 is grammatically incorrect, and should recite "said status-characterizing information ~~collecting~~ obtained before or during...." [p.4, line 1]. Appropriate correction is required.

Claims 8-10 are objected to under 37 CFR 1.75(c) as being in improper form as they depend from a withdrawn claim (claim 6) See MPEP § 608.01(n).

### *CLAIMS UNDER EXAMINATION*

Claims 1, 2, 4, 5, 8-10, 15-21, 23-25, and 30-31 are herein under examination. Applicant's election of Species I-A (cells collected from human), II-(i) (status-characterizing information obtained from blood sample measurements), III-A (bioelectronic information), and IV-C in the response filed 3/15/2006 is noted. It has been determined that claim 22 requires capillary data obtained from a subject's hair system. Therefore claim 22 has been withdrawn, as it reads on the nonelected species directed to information obtained from hair samples. Claims 3, 6, 7, 11-14, 22, and 27-29 are now withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

### CLAIM REJECTIONS - 35 USC §112, 1<sup>st</sup> Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 8-10, 15-21, 23-25, and 30-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for determining parameters for deferred-use protocols using an expert system, as set forth in the previous office action mailed 09/12/2006. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant's arguments, filed 02/12/2007, that the Specification provides sufficient guidance for processing measurements made on samples, processing status-characterizing information for determining the subject's identity data, and performing an identification of batches of cells by consulting a cell management system are persuasive.

Applicant's arguments that the Specification provides sufficient guidance for determining parameters of a deferred-use protocol for immunocompetent cells, as required by claims 1 and 19, wherein said parameters are determined using an expert system, as required by claims 4, 5, 23, and 24, are not persuasive for the following reasons.

In response to applicant's arguments, the instant application is an invitation to experiment to determine a deferred-use protocol and parameters thereof without any explanation of what the desired deferred-use end goal is and without any clear explanation of what particular input is required achieve this goal (i.e. subject's identity data). While the applicant points to a non-limiting example of a deferred-use protocol [p.16], this use "depends on parameters and therapeutic indications for re-use." Therefore this example does not provide sufficient guidance as to how one of skill in the art would be able to determine the parameters of the claimed deferred-use protocol. This problem is further compounded by the fact the no particular future use has been disclosed by applicant. Therefore, the specification does not provide any concrete example of the intent of the claimed methods or systems.

As set forth in the previous office action mailed 09/12/2006, Shortliffe et al. teach the development of an expert system for oncology protocol management based on patient diagnostic data, laboratory test, and specific treatment protocol information. However, the system of Shortliffe et al. required the development of a unique data structure to guide knowledge acquisition [35.4.2] and [Fig. 35-3]. In particular, parameters used in their expert system were determined from specific attributes of patient data [35.4.2, ¶ 3]. Shortliffe et al. have encoded knowledge from oncology patients. As each type of cancer requires specific diagnostic and prognostic protocols, it is unlikely that these protocols are directly applicable for deferred-use protocols for immunocompetent cells. Thus, given the nature of the instantly claimed invention, an expert system would need to be developed in order to determine the parameters necessary for use in the claimed deferred-use protocol. Sufficient information and guidance is required to develop, test, and validate such an expert system, as supported by the teaching of the prior art, above. Although the level of skill in the art of culturing cells and measuring cell parameters is high, the Examiner maintains that one skilled in the art would

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require undue experimentation to predictably practice the instantly claimed invention. [Wands factors (1), (2), (6), (7)].

### **CLAIM REJECTIONS - 35 USC § 112**

Claims 1, 2, 4, 5, 8-10, 15-21, 23-25, and 30-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 19 are rejected for the following reasons. Claims which are directly or indirectly dependent from claim(s) 1 and 19 are also included as rejected herein, due to said dependence.

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Claims 1 and 19 are directed to a method and system for "managing batches of immunocompetent cells." However, the instant claims result in "providing said cell treatment entity with said identified batches of cells and with said deferred-use protocol parameters." Applicant's arguments are not illuminating. The Examiner maintains that it remains unclear in what way the steps of instant claim 1 achieve the purpose of the preamble, as the preamble does not address the determination of deferred use protocol parameters. Clarification is again requested via clearer claim language.

Claims 1 and 19 recite "a sum of immunity information stored in the walls of the collected immunocompetent cells." The term "walls" is not an art recognized term. As the specification does not define or fully and completely describe "walls" for carrying out the intended function, one skilled in the art would not know the metes and bounds of this term. Clarification is requested via clearer claim language.

### CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, 8, 15-19, 20, 25, 30, and 31 are rejected under 35 U.S.C. 102 (a) as being anticipated by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5).



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In the absence of an English translation of WO/1999/053030, the automatic translation function on "Google Patents" was used to translate WO/1999/053030 and is relied upon herein as the primary reference. It is noted that the instant claims are broad with respect to "deferred-use protocols." Therefore, the Examiner has broadly interpreted this limitation to encompass the teachings of the prior art as set forth below.

Lefesvre et al. teach a method and system for management of batches of immuno-qualified cells, in particular of lymphocytes (i.e. immunocompetent cells) or monocytes, for differed uses [Abstract]. Lefesvre et al. [Fig. 1] teach the following aspects of instant claims 1, 19, 30, and 31:

- Means for preserving cells (e.g. deep freezing)
- Multiple storage centers
- Means for patient data collection (i.e. identification)
- Means for storing data comprising lymphocyte data from multiple batches
- Means for collecting information characteristic of the status of health of a subject
- Means for therapeutic indication for re-use
- Means for receiving a request for batches for re-use
- Cell treatment center

Lefesvre et al. also teach the following aspects of the instantly claimed invention:

- Personal libraries for patients personal library preserving a sum of immunizing information stored in the taken immuno-qualified cells, and, response to a treatment; a treatment of whole or part of the immunizing information accumulated in the aforementioned personal library, and localization of one or more stored batches of

immuno-qualified cells, followed by a transfer of this or these batches towards a cellular processing center requiring (i.e. expert system) [p.2, ¶ 2], as in claims 1, 4, and 25.

- Protocols for control of identification which can in particular comprise a new cellular identification, handing-over in suspension of the lymphocytes or monocytes in a culture medium, checking operations of quality (i.e. checking for annihilation of antibodies), and - a re-use of the lymphocytes in the patient [p.4, ¶ 2], as in claims 1, 8, 17, and 18.
- Transfer of data and parameters directly involved in the process of batch management [p.4, ¶ 4], as in claim 1.
- Gene therapy protocols [p.2, ¶ 12], as in claim 15.
- Plurality of sites of cryogenic storage designed to receive the batches of immuno-qualified cells [p.3, ¶ 2], as in claim 16.
- Taking blood from a patient, a treatment of taken blood and a separation of the lymphocytes and/or monocytes, a cellular identification, a fractionation to carry out a whole of batches of lymphocytes and/or monocytes, a preparation of the lymphocytes and/or monocytes, including dehydration, grouping and setting in cryogenic storage of N batches of lymphocytes and/or monocytes [p.3, ¶ 9], as in claims 18 and 20.

As the specification does not provide any limiting definitions for the claimed “expert system”, “deferred use protocol”, or “deferred use protocol parameters” that would serve to exclude the above teachings of Lefesvre et al., the Examiner has broadly and reasonably interpreted this instant claims to encompass the teaching of Lefesvre et al. Therefore, Lefesvre et al. anticipates instant claims 1, 4, 8, 15-19, 20, 25, 30, and 31.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 8-10, 15-19, 20, 21, 23, 24, 25, 30, and 31 are rejected under 35 U.S.C. 103(a) as being made obvious by Lefesvre et al. (WO/1999/053030; Publication Date: 10/21/1999, p.1-5), in view of Barnhill et al. (US Pat. 6,248,063; Filed Dec. 22, 1997), Schettler et al. (Nephrol. Dial. Transplant, 1998, Vol. 13, p.2588-2593), and Cha et al. (Physiol. Meas., 1994, Vol. 15, p. 129-137).

Lefesvre et al. teach a method and system for management of batches of immuno-qualified cells, in particular of lymphocytes (i.e. immunocompetent cells) or monocytes, for differed uses [Abstract], as set forth above and applied to claims 1, 4, 15-19, 20, 25, 30, and 31.

Lefesvre et al. do not specifically teach an expert system that "provides an interpretation" of information, as in claims 5, 23, and 24, oxidative stress protocols, as in claims 9 and 10, or bioelectronic information collected from blood, as in claims 2 and 21.

Barnhill et al. teach a method and system for diagnosing, screening, or prognosing diseases in humans or animals [Abstract]. The invention includes means entering patient data into a neural network (i.e. expert system) used for producing diagnostic or prognostic values (i.e. data interpretation) [Col. 12, lines 50-67], and determining appropriate parameters [Col. 19, lines 10-25], as in claims 5, 23, and 24. Patient biological data may be derived from measurement of any biological parameter and may include immunocytochemical data (i.e. immunity information) [Col. 11, lines 25-50], and may be derived from analysis of cells [Col. 11, 50-55], and may include results from genetic analysis [Col. 11, lines 59-62], as in claims 4 and 5. Therefore Barnhill et al. teaches Barnhill et al. also teach methods for collecting biological fluid (i.e. blood) from a patient [Col. 15, lines 5-15], and clinical analysis of blood samples [Col. 20, lines 29-30]. The Examiner has broadly interpreted the diagnostic and prognostic values of Barnhill et al. as teachings for deferred-use protocol parameters, as they are directly involve in disease diagnosis and treatment.

Schettler et al. teach protocols for measuring oxidative stress in dialysis patients during treatment [Abstract]. Specifically, Schettler et al. teach the measurement of free radicals in blood cells as an indicator of oxidative stress caused in patients undergoing dialysis treatment [p.2592, Col. 1, ¶ 1-3] and [p.2589, Subjects and Methods], as in claims 9 and 10.

Cha et al. teach an electronic method for obtaining bioelectronic information by processing previously collected patient blood samples. Cha et al. specifically teach obtaining resistance (i.e. resistivity) and reactance values [Abstract], as in claims 2 and 21.

Thus, it would have been obvious to some one of ordinary skill in the art at the time of the instant invention to use the method for managing immunocompetent cell batches taught by Lefesvre in combination with the expert system taught by Barnhill et al., where the motivation would have been to improve patient treatment with an automated network-based system for

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obtaining diagnostic and prognostic information [Barnhill et al., Col. 7, lines 25-30], with the oxidative stress method taught by Schettler et al., where the motivation would have been to monitor oxidative stress in patients undergoing treatments with ex vivo devices (i.e. dialysis) [Schettler, p.2591, Col. 1 ¶ 1], and with the bioelectric method taught by Cha et al., where the motivation would have been to improve accuracy of patient blood sample measurements [Cha et al., p.136, ¶ 3 and 4], thus resulting in the practice of the instant invention. One of ordinary skill in the art would also have had a reasonable expectation of successfully combining the above teachings as both Barnhill et al., Schettler et al., and Cha et al. are directed to intended uses of biological measurements that are obvious to an artisan.

#### **OBVIOUSNESS TYPE DOUBLE PATENTING**

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of

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record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of US 6,415,201 (Issued Jul. 2, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention causing the inventions to have overlapping embodiments. The instant claims and those of US 6,415,201 both are directed to methods and system for managing batches of cells collected from subjects for deferred use, with minor variations. For example, instant claim 1 requires collection of immunocompetent cells, whereas US 6,415,201 requires collection of haemopoietic cells. Therefore, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to collect immunocompetent cells, instead of haemopoietic cells, as blood cells are clearly a component of the immune system.

## CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

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MICHAEL BORIN, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.